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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/731,551	12/08/2003	Todd K. Whitehurst	05-00537-01	4571

71422 7590 12/03/2008

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EXAMINER	
EVANISKO, GEORGE ROBERT	
ART UNIT	**PAPER NUMBER**
3762	
MAIL DATE	**DELIVERY MODE**
12/03/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/731,551	WHITEHURST ET AL.	
	Examiner	Art Unit	
	George R. Evanisko	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 August 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18-21,24-27 and 30-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18-21 and 24-27, and 30-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 18, 20, 21, 32, 33, and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hill et al (WO 02/34330 A2) in view of Hill et al (WO 02/34327 A2--hereinafter Hill '327). Hill discloses the use of his system for angina (e.g. page 3, line 19) and the stimulation of cutaneous nerves and the chest wall (e.g. page 8, lines 14-21), other nerves located "in the pectoral region of the left chest located beneath the facia on the muscle and motor point of the pectoral muscle with stimulation of the musculocutaneous and thoracic nerves" (page 4, line 8), "the electrodes may be positioned in the auxiliary region beneath the left arm with stimulation provided to the musculocutaneous, bachialcutaneou and thoracodorsal nerves"

(page 4, line 10) and "any combination being utilized...cardiac neurons" (page 22, lines 1-10) and shows and describes the use of stimulating the nerves in the chest wall/ribs at the T2 and T3 levels in figure 1B (page 8) and therefore stimulates the intercostal nerves and/or a cutaneous intercostal nerve branch since Hill stimulates the ventral branch of thoracic nerves as seen and described in Hill's specification. In addition, Hill discloses the use of sensors for internal or external control of the stimulation (pages 4 and 14 and table II), the use of an external programmer to program the stimulator with pulse parameters (pages 12, 14, etc), and the excitatory stimulation (page 22). Finally, Hill discloses that the stimulation parameters can be modified/adjusted so optimal treatment can be delivered (e.g. page 14) and therefore provides motivation to modify the stimulation parameters. NOTE—The claims do not state that the electrodes are placed "directly" at the cutaneous nerves or that they are "directly" electrical stimulated. Since Hill discloses electrical stimulation of cutaneous nerves and/or stimulation of intercostal nerves, the electrical stimulation will inherently electrically stimulate these cutaneous nerves, such as the lateral and anterior cutaneous branch, due to the electrical conduction of the nerves (in the alternative, see the 103 rejections below).

Hill does not disclose the stimulation being less than 100 Hz (or less than 50 Hz). Hill '327 teaches that it is known to use stimulation from "about 50-100 Hz" (e.g. page 10) to effectively treat angina. In addition, since "about 50...Hz" is used, this will provide for the claim limitation of less than 50 Hz since "about" means slightly above or below 50 (in the alternative, see the 103 rejection below). It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate in the angina stimulation method and system as taught by Hill, the use of stimulation of about 50-100 Hz as taught by Hill '327, since such a

modification would provide the predictable results of an angina system and method that uses a stimulation of about 50-100 Hz that will effectively treat angina.

In the alternative, for the stimulation of the lateral or anterior cutaneous branch of the intercostal nerves, Hill does not disclose the direct electrical stimulation of the lateral or anterior cutaneous branch but does disclose stimulating numerous nerves in the chest and rib area and cutaneous nerves. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the stimulation for angina as taught by Hill, with the stimulation of other nerves in the chest/rib area, such as the lateral or anterior cutaneous nerves since it would have been "obvious to try" other nerves in the chest area to determine the proper nerve(s) to relieve angina pain to provide the predictable results of determining the best nerve to relieve angina since physiological differences between patients require different stimulation locations and parameters. In addition, it would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the location of the stimulation as taught by Hill with the stimulation of the anterior or lateral cutaneous branch, because Applicant has not disclosed that the stimulation of the anterior or lateral cutaneous branch provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the different stimulation areas as taught by Hill, because it provides effective relief from angina.

Therefore, it would have been an obvious matter of design choice to modify Hill to obtain the invention as specified in the claim(s).

Claims 19 and 24-27 are rejected under 35 U.S.C. 103(a) as obvious over Hill et al in view of Hill '327 (the "modified Hill"). Most of the claim limitations are addressed above in the 103 rejection. In addition, modified Hill states that the IMD can have the electrodes carried on the surface of the implantable device (page 8, lines 28-30) and are therefore leadless stimulators that will require the stimulator(s) to be placed adjacent the nerves and/or between the ribs.

In the alternative, modified Hill discloses the claimed invention using electrodes on the surface of the IMD and stimulating the T2 and T3 levels and multiple different nerves except for the leadless stimulator capable of being placed adjacent the nerves and/or between the ribs and being two or more stimulators. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the surface electrodes system and method as taught by modified Hill, with the leadless stimulator capable of being placed adjacent the nerves and/or between the ribs and the system using two or more stimulators to stimulate the nerves since it was known in the art that: leadless stimulators are used to place the stimulator adjacent nerves and or locations such as between the ribs to provide the predictable results of stimulating the particular nerves to provide a stimulator that only requires minimally invasive insertion/surgery of the stimulator to directly stimulate the appropriate nerves for therapy for the patient; and that more than one stimulator can be used to provide the predictable results of allowing the stimulators to treat different areas of the body, such as different nerves, without multiple leads or a large IMD and that can provide different independent pulses to the different areas.

Claims 30 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over modified Hill. Modified Hill discloses the claimed invention providing stimulation to the nerves

through a lead and electrode (figure 1C) and using the sensor to adjust the pulse parameters (pages 5 and 12) and other ways to modify the pulse parameters (e.g. page 14) to provide the appropriate pulses for therapy, but does not disclose the pulses using less than 1.5 mA and being less than 50 Hz. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the nerve stimulation system and method as taught by modified Hill with the pulses using less than 1.5 mA and being less than 50 Hz, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. In addition, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the nerve stimulation system and method as taught by modified Hill, with the pulses using less than 1.5 mA and the being less than 50 Hz since it was known in the art that nerve stimulation systems and method use pulses using less than 1.5 mA and being less than 50 Hz to provide the predictable results of a therapeutic pulse and frequency to the patient without causing pain to the patient that effectively stimulates the patient.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection necessitated by amendment. The examiner has considered the information in response to the 1.105 request and has used and relied upon that information in the above rejection to the same extent that the Applicant has specifically pointed out the intercostal nerves and branches in the some 75 pages provided--i.e. as relating to the general chest area. In addition, the applicant's arguments do not point out the errors in the action or provide a statement that the elements relied on for the previous office actions 103 rejections are not

considered to be common knowledge or are not well-known in the art and are therefore taken to be admitted prior art.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R. Evanisko whose telephone number is 571 272 4945. The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571 272 4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/George R Evanisko/
Primary Examiner, Art Unit 3762

GRE
11/30/08